



**[Billing Code 4140-01-P]**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Government-Owned Inventions; Availability for Licensing**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S.

Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Benjamin Hurley; tel. 240-669-5092; [benjamin.hurley@nih.gov](mailto:benjamin.hurley@nih.gov). Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

**SUPPLEMENTARY INFORMATION:** Technology description follows:

## **FRugally Optimized DNA Octamer (FRODO): DNA Vector and Uses Thereof For Detecting HIV and SIV**

### **Description of Technology:**

Quantitative polymerase chain reactions (qPCRs) are commonly employed to enumerate genes of interest among particular biological samples. Insertion of PCR amplicons into plasmid DNA is a mainstay for creation of known quantities of target sequences to standardize quantitative PCRs. Typically, one amplicon is inserted into one plasmid construct, the plasmid is then amplified, purified, serially diluted, and then quantified to be used to enumerate target sequences in unknown samples. As qPCR is often used to detect multiple amplicons simultaneously, individual qPCR standards are often desired to be normalized one to another. Unlike prior methods using separate plasmid constructs for each target sequence, FRODO incorporates eight amplicons into one plasmid construct ensuring equivalent template copy numbers for all amplicons. Amplifying, purifying, diluting and quantifying one plasmid construct rather than eight individual constructs streamlines standard curve qPCR analyses, reducing reagents and simplifying normalization between amplicons.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

### **Potential Commercial Applications:**

- Clinical Detection, Monitoring of Nucleic Acid Markers of HIV and Immunological Health: FRODO may be used to efficiently quantify target sequences in unknown samples.
- FRODO is a single plasmid containing 8 amplicons which can be used to quantify several different strains of SIV and HIV, cell number equivalents for humans and

nonhuman primates, T cell receptor excision circles (humans and nonhuman primates), and bacterial 16S and ampicillin resistance DNA.

- FRODO may offer improved, more affordable, highly-sensitive nucleic acid-based HIV quantification and/or diagnostic response times, enhancing patient treatment and interventions.
- FRODO can be used to quantify levels of bacterial DNA in clinical samples to determine potential sepsis.
- This technology is especially useful in translational HIV research in which human and nonhuman primate models are used to study HIV pathogenesis, informing public health responses.

**Competitive Advantages:**

- A simplified workflow for qPCR testing. Amplifying, purifying, diluting and quantifying one plasmid construct rather than multiple, individual constructs streamlines standard curve qPCR analyses, reducing reagents and simplifying normalization between amplicons.
- At present, there are a number of antibody-based clinical tools that may be used for diagnosing/detecting HIV, but there are fewer products that affordably detect/monitor nucleic acids of HIV within cells, and immunological health, and efficacy of medicaments aimed at reducing cells infected with HIV.

**Inventors:** Jason Brenchley and Charlotte Langner, both of NIAID.

**Publications:**

Langer, Charlotte A. and Brenchley, Jason M.; Frugally Optimized DNA Octomer (FRODO) qPCR Measurement of HIV and SIV in Human and Nonhuman Primate Samples; *Current Protocols*, 2021.

**Intellectual Property:** HHS Reference No. E-024-2021; US Provisional Application No. 63/128,392

**Licensing Contact:** To license this technology, please contact Benjamin Hurley at 240-669-5092 or [benjamin.hurley@nih.gov](mailto:benjamin.hurley@nih.gov), and reference E-024-2021.

**Collaborative Research Opportunity:** The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this invention. For collaboration opportunities, please contact Benjamin Hurley; 240-669-5092, [benjamin.hurley@nih.gov](mailto:benjamin.hurley@nih.gov).

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